

PATENT APPLICATION TRANSMITTAL LETTER
(Small Entity)

Docket No.
P1178USA

TO THE ASSISTANT COMMISSIONER FOR PATENTS

Transmitted herewith for filing under 35 U.S.C. 111 and 37 C.F.R. 1.53 is the patent application of:

Bryan, Vincent; Kunzler, Alex

For:

DRILL HEAD FOR USE IN PLACING AN INTERVERTEBRAL DISC DEVICE

Enclosed are:

- ☒ Certificate of Mailing with Express Mail Mailing Label No. **EM549228619US**
- ☒ Two sheets of drawings.
- ☐ A certified copy of a application.
- ☒ Declaration ☒ Signed. ☐ Unsigned.
- ☒ Power of Attorney
- ☐ Information Disclosure Statement
- ☐ Preliminary Amendment
- ☒ Declaration Verified Statement(s) to Establish Small Entity Status Under 37 C.F.R. 1.9 and 1.27.
- ☒ Other: **Return Postcard; Express Mail Certification**

CLAIMS AS FILED

For	#Filed	#Allowed	#Extra	Rate	Fee
Total Claims	18	- 20 =	0	x \$11.00	\$0.00
Indep. Claims	2	- 3 =	0	x \$41.00	\$0.00
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>					\$0.00
BASIC FEE					\$395.00
TOTAL FILING FEE					\$395.00

- ☒ A check in the amount of **\$395.00** to cover the filing fee is enclosed.
- ☒ The Commissioner is hereby authorized to charge and credit Deposit Account No. **07-0181** as described below. A duplicate copy of this sheet is enclosed.
 - ☐ Charge the amount of as filing fee.
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 - ☐ Charge any additional filing fees required under 37 C.F.R. 1.16 and 1.17.
 - ☒ Charge the issue fee set in 37 C.F.R. 1.18 at the mailing of the Notice of Allowance, pursuant to 37 C.F.R. 1.311(b).

Dated:

60 of Apr, 1997

Todd S. Parkhurst
Signature

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DRILL HEAD FOR USE IN PLACING AN INTERVERTEBRAL DISC DEVICE

Background of the Invention

This invention relates generally to drill heads and more particularly to drill heads for use in placing an intervertebral disc device.

The herniation of a spinal disc and the often resultant symptoms of intractable pain, weakness, sensory loss, incontinence and progressive arthritis are among the most common of debilitating processes affecting mankind. If a patient's condition does not improve after conservative treatment, and if clear physical evidence of nerve root or spinal cord compression is apparent, and if correlating radiographic studies (i.e., MRI or CT imaging or myelography) confirm the condition, surgical removal of the herniated disc may be indicated. The process of discectomy -- as the name implies -- involves the simple removal of the disc without attempt to replace or repair the malfunctioning unit. In the United States in 1985, over 250,000 such operations were performed in the lumbar spine and in the cervical spine.

Statistics suggest that present surgical techniques are likely to result in short-term relief, but will not prevent the progressive deterioration of the patient's condition in the long run. Through better pre-operative procedures and diagnostic studies, long-term patient results have improved somewhat. But it has become clear that unless the removed disc is replaced or the spine is otherwise properly supported, further degeneration of the patient's condition will almost certainly occur.

In the mid-1950's and 60's, Cloward and Smith & Robinson popularized anterior surgical approaches to the cervical spine for the treatment of cervical degenerative disc disease and related disorders of the vertebrae, spinal cord and nerve root; these surgeries involved disc removal followed by interbody fusion with a bone graft. It was noted by Robinson (Robinson, R.A.: The Results of Anterior Interbody Fusion of the Cervical Spine, J. Bone Joint Surg., 440A: 1569-

1586, 1962) that after surgical fusion, osteophyte (bone spur) reabsorption at the fused segment might take place. However, it has become increasingly apparent that unfused vertebral segments at the levels above and below the fused segment degenerate at accelerated rates as a direct result of this fusion. This has led some surgeons to perform discectomy alone, without fusion, by a posterior approach in the neck of some patients. However, as has occurred in surgeries involving the lower back where discectomy without fusion is more common as the initial treatment for disc herniation syndromes, progressive degeneration at the level of disc excision is the rule rather than the exception. Premature degenerative disc disease at the level above and below the excised disc can and does occur.

Spine surgery occasionally involves fusion of the spine segments. In addition to the problems created by disc herniation, traumatic, malignant, infectious and degenerative syndromes of the spine can be treated by fusion. Other procedures can include bone grafts and heavy duty metallic rods, hooks, plates and screws being appended to the patient's anatomy; often they are rigidly and internally fixed. None provide for a patient's return to near-normal functioning. Though these procedures may solve a short-term problem, they can cause other, longer term, problems.

A number of attempts have been made to solve some of the problems described above by providing a patient with spinal disc prostheses, or artificial discs of one sort or another. For example, Steffee, U.S. Patent 5,031,437, describes a spinal disc prosthesis having upper and lower rigid flat plates and a flat elastomeric core sandwiched between the plates. Frey et al., U.S. Patents 4,917,704 and 4,955,908, disclose intervertebral prostheses, but the prostheses are described as solid bodies.

U.S. Patents 4,911,718 and 5,171,281 disclose resilient disc spacers, but no inter-connective or containing planes or like elements are suggested, and sealing the entire unit is not taught.

Co-pending, related U.S. Patent Application Serial No. 08/681,230 incorporated herein by reference, provides a vertebral disc endoprosthesis which addresses these shortcomings of the prior art. The endoprosthesis comprises a resilient body formed of a material varying in stiffness from a relatively stiff exterior portion to a relatively supple central portion. A concaval-convex means at least partly surrounds that resilient body so as to retain the resilient body between adjacent vertebral bodies of a patient's spine. If medical considerations so indicate, several disc endoprosthesis can be combined with one or more endoprosthetic vertebral bodies in an entire assembly.

In order to place the above endoprosthesis in a patient's spine, the bone of the two opposing intervertebral bodies must be prepared in such a manner so as to accept the concaval-convex shape of endoprosthesis. However, currently available drill heads are not always capable of being fit into the narrow space between two opposing intervertebral bodies. Further, the narrow space between two opposing intervertebral bodies cannot always be expanded to allow admittance of currently available drill heads.

Thus, it is an object of the instant invention to provide a drill head which can fit within the narrow space between two opposing intervertebral bodies.

It is another object of the instant invention to provide a drill head which can prepare the bone of the two opposing intervertebral bodies to accept the concaval-convex shape of an endoprosthesis.

These and other objects and advantages of the instant invention will be apparent from the following description and drawings.

Summary of the Invention

The instant invention overcomes the deficiencies of the prior art devices by providing a drill or milling head with a narrow profile which can fit in the space between two opposing intervertebral bodies. Moreover, the device can handle torque and power in sufficient amounts as to be capable of milling on a surface and acting in a direction angled away from the direction of device entry into the space between those intervertebral bodies.

The drill head of the instant invention is provided with a form cutter having a convex shape so as to prepare the bone of vertebral bodies to accept the concave-convex shape of an endoprosthesis. In addition, the cutter may have the ability to cut in the direction of tool entry into the space.

Brief Description of the Drawings

Figure 1 is a side view of one embodiment of the instant invention.

Figure 2 is a cross-sectional view of the embodiment of Figure 1.

Figure 3 is a partial cross-sectional view of an alternate embodiment of the instant invention.

Detailed Description of the Invention

While the invention will be described in connection with a preferred embodiment and procedure, it will be understood that it is not intended to limit the invention to this embodiment or procedure. On the contrary, it is intended to cover all alternatives, modifications, and equivalents as may be included within the spirit and scope of the invention as defined by the appended claims.

One embodiment of the drill head of the present invention is depicted in Figures 1 and 2. The drill head 20 generally comprises a form cutter portion 22, drive means 24, and attachment means 26. In accordance with the invention, the form cutter profile imparts a shape to the bone of the intervertebral bodies which mates with the predetermined endoprosthesis surface shape.

As seen in Figure 2, the drill head 20 includes a form cutter 29 carried by a housing 31 having an upstanding wall 35 and a shaft support 37 for supporting the form cutter 29. The housing 31 further includes an elongated shaft portion 40 which houses the drive shaft discussed below. To provide a drill head which can prepare the bone of the two opposing intervertebral bodies to accept the concaval-convex shape of an endoprosthesis, the illustrated form cutter 29 has a convex milling surface 42. This convex surface 42 of the form cutter 29 functions to provide the bone of a vertebral body with a mating shape complementary to the concaval-convex shape of the endoprosthesis which is the subject of co-pending U.S. Patent Application Serial No. 08/681,230. As illustrated, this tool drill or milling head can mill in a direction angled away from the direction of device entry into the space between the intervertebral bodies. That edge 44 provides the cutter 29 with the ability to cut in the direction of tool entry into the space between two opposed vertebral bodies.

The form cutter 29 further includes an outwardly extending edge 44 about its perimeter. In addition, the undersurface 47 of the form cutter 29 may be provided with a beveled gearing surface 49. Alternately, the beveled gearing surface 49 may be provided about the undersurface of the upstanding edge.

The form cutter 29 is provided with a shaft 51 extending perpendicularly from its undersurface. The form cutter 29 is supported within the housing 31 by the cooperation between the shaft 51 and the shaft support 37. This arrangement permits the form cutter 29 to be removed

from the housing 31 by separating the shaft 51 from the shaft support 37. Thus, when the cutter dulls, it can be replaced with a new cutter to ensure accurate and effective performance of the drill head.

In order to provide a drill head which can fit within the narrow space between two opposing intervertebral bodies in accordance with the invention, the maximum height of the illustrated form of the cutter portion 22 of the drill head 20 is nine millimeters. Providing the bevel gearing surface 49 on the form cutter 29 allows the drill head 20 to be manufactured with such a narrow profile. This arrangement eliminates the need for a separate gear and form cutter which would likely add to the height of the drill head. Because of its profile, the drill head 20 of the present invention can fit in the narrow space between two opposing intervertebral bodies in the cervical spine of a patient.

To provide a driving force to the form cutter 29, the drill head 20 is provided with drive means 24. As shown in Figure 2, the drive means 24 comprises a drive shaft 54 operatively coupled at its distal end to the form cutter 29 and at its proximal end to a drive source 61. The distal end of the drive shaft 54 is supported by a journal 56 within the housing and is provided with a pinion gear 59. As mentioned above, the undersurface 47 of the form cutter 29 is provided with a beveled gearing surface 49. When the drive shaft 54 rotates, the pinion gear 59 also rotates and cooperates with the beveled gearing surface 49 of the form cutter 29, thereby causing the form cutter 29 to rotate about the shaft 51.

The proximal end of the drive shaft 54 is operatively coupled to a suitable drive source 61 by coupling means 63. Although a drive source is not shown in the embodiment of Figures 1 and 2, it should be understood that the drive source shown by Figure 3 or its functional equivalent could be employed. The illustrated drive source 61 comprises a suitable motor 65 having mating

coupling means 69. The motor 65 imparts a driving force to the drive shaft 54 via the mating of the coupling means 63, 69.

As shown in Figure 2, the form cutter 29 is not necessarily oriented at a right angle with respect to the drive shaft 54. In the illustrated device, the angle between the support shaft 51 of the form cutter 29 and the drive shaft 51 is approximately 96° to provide a designed orientation to the vertebral bone surface being milled.

The housing 31, which houses the form cutter 29 and the drive shaft 54, is provided at its proximal end with an attachment means 71. The attachment means 71 allows the drive source to be attached to the drill head 20 of the present invention. In the embodiment of Figure 2, the drive source is attached to the drill head 20 via threads 73. However, alternate equivalent attaching means could be employed to attach the drive source to the drill head 20. The housing 31 is also provided with a ring 75 about its circumference.

An alternate embodiment of the drive means 24 used in the drill head is shown in Figure 3. Rather than being driven by a gear and pinion mechanism, the drill head 20 is driven by a drive belt 78. To accommodate the belt driving arrangement, the form cutter 29 is provided with a groove 80 about its perimeter rather than being provided with a beveled gearing surface. The groove 80 interacts with the drive belt 78 to provide a driving force to the form cutter 29. This alternate driving arrangement enables the drill head 20 to be manufactured with a narrow profile.

As mentioned above, in this embodiment of the invention, the drive means 24 comprises a drive belt 78 which is operatively coupled to the form cutter 29 at the distal end of the drill head 20. The belt 78 loops around the form cutter 29 within the groove 80. At the proximal end of the drill head 20, a drive shaft 82 is provided which is operatively coupled to a suitable drive source 61. The drive shaft 82 is provided with a pulley 85 about which the belt 78 is looped. At

one end, the drive shaft 82 is supported by the housing 31 with suitable means such as a bearing or bushing 87. At its opposite end, the drive shaft 82 is provided with a coupling means 63 for coupling to a suitable drive source 61. When the drive source 61 acts upon the drive shaft 82 and causes it to rotate, the pulley 85 is caused to rotate, thereby driving the belt 78 and causing the form cutter 29 to rotate.

To accommodate the driving means arrangement of this alternate embodiment, the housing 31 is provided with a perpendicular extension 90 at the proximal end of the drill head 20. The extension 90 is provided with the attachment means 71 for attaching the drill head 20 to a suitable drive source 61. It is within the extension 90 that the drive shaft 82 is coupled to the drive source 61. The housing extension 90 is further provided with an intermediate support member 92 for providing additional support to the drive shaft 82.

Claims

1. A drill head for preparing the bone of two opposing intervertebral bodies to accept a predetermined shape of an endoprosthesis comprising:

a form cutter having a profile capable of imparting a shape to the bone of intervertebral bodies which mates with the predetermined endoprosthesis surface shape;

drive means for providing a driving force to the form cutter; and

means for housing the form cutter and the drive means,

wherein the profile of the form cutter is of a height capable of being admitted into the space between two opposing intervertebral bodies and the head can perform milling action in a direction angled away from the direction of head entry into a space between opposed bodies.

2. The drill head of Claim 1 wherein the form cutter has a convex shape.

3. The drill head of Claim 2 wherein the form cutter is provided with a beveled gearing surface.

4. The drill head of Claim 2 wherein the form cutter is provided with a groove about its perimeter.

5. The drill head of Claim 1 wherein the drive means comprises a drive shaft operatively coupling the form cutter to a drive source.

6. The drill head of Claim 5 wherein a distal end of the drive shaft is provided with a pinion gear which cooperates with the form cutter to impart a rotary motion to the form cutter.

7. The drill head of Claim 5 wherein a proximal end of the drive shaft is provided with a coupling means for coupling the drive shaft to the drive source.

8. The drill head of Claim 1 wherein the drive means comprises a belt operatively coupling the form cutter to a drive source.

9. The drill head of Claim 8 wherein the belt loops about the perimeter of the form cutter.

10. The drill head of Claim 8 wherein the drive means further comprises a drive shaft operatively coupled to the belt.

11. The drill head of Claim 10 wherein the drive shaft is provided with a pulley about which the belt is looped.

12. The drill head of Claim 11 wherein the drive shaft is further provided with a coupling means for coupling the drive shaft to the drive source.

13. The drill head of Claim 1 wherein the housing is provided with attachment means for attaching the drill head to a drive source.

14. The drill head of Claim 1 wherein the maximum height of the profile of the form cutter is approximately nine millimeters.

15. The drill head of Claim 1 where in the cutter is provided with a cutting edge so as to give the drill head the ability to cut in the direction of tool head entry into the space.

16. A drill head for preparing the bone of two opposing intervertebral bodies to accept the concaval-convex shape of an endoprosthesis comprising:

a form cutter having a support shaft capable of imparting a concave shape to the bone of intervertebral bodies;

drive means for providing a driving force to the form cutter, the drive means including a drive shaft; and

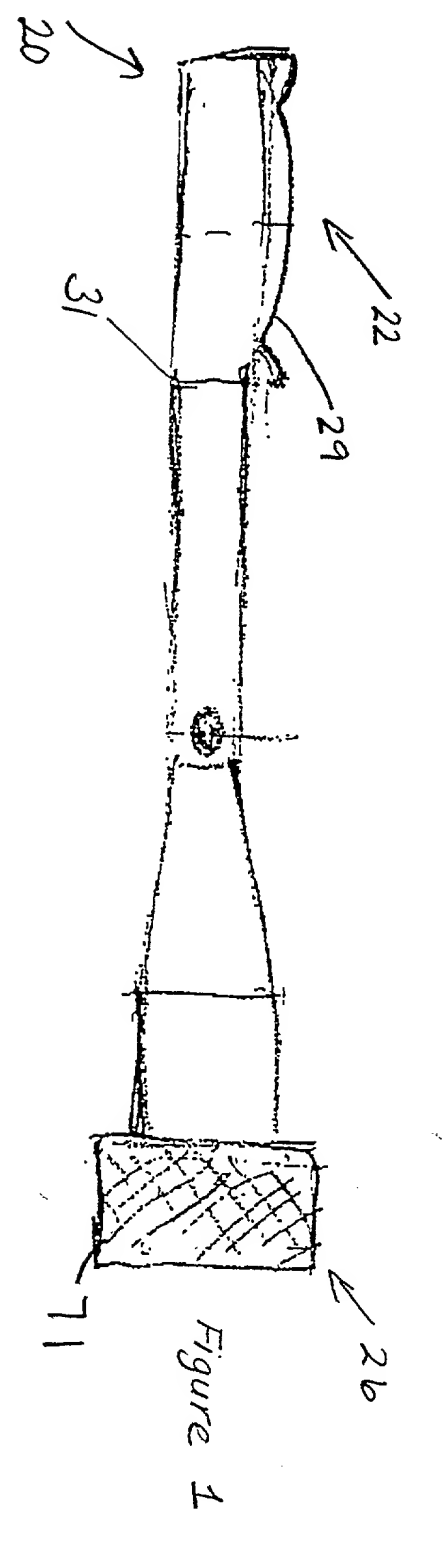
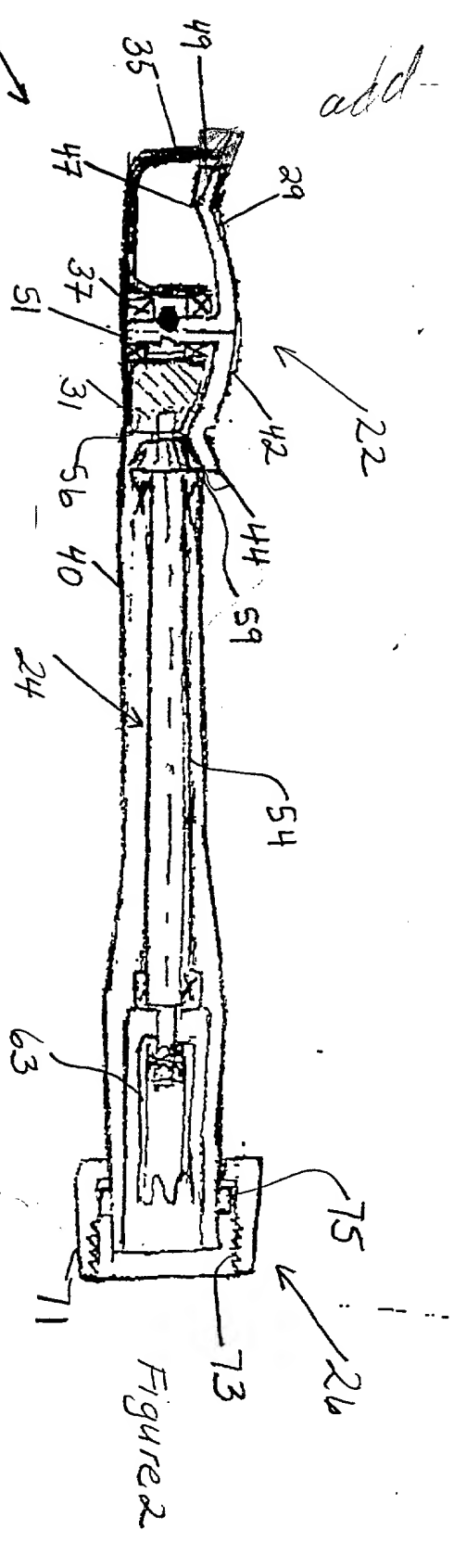
means for housing the form cutter and the drive means,

wherein the angle between the support shaft of the form cutter and the drive shaft is approximately 96°.

17. The drill head of Claim 16 wherein the form cutter has a predetermined profile.
18. The drill head of Claim 17 wherein the maximum height of the profile of the form cutter is approximately nine millimeters.

Abstract

A drill head for preparing the bone of two opposing intervertebral bodies to accept the concaval-convex shape of an endoprosthesis includes a form cutter portion, drive means, and a housing. The form cutter having such a profile allows the drill head to fit in the narrow space between two opposing intervertebral bodies in the cervical spine of a patient.



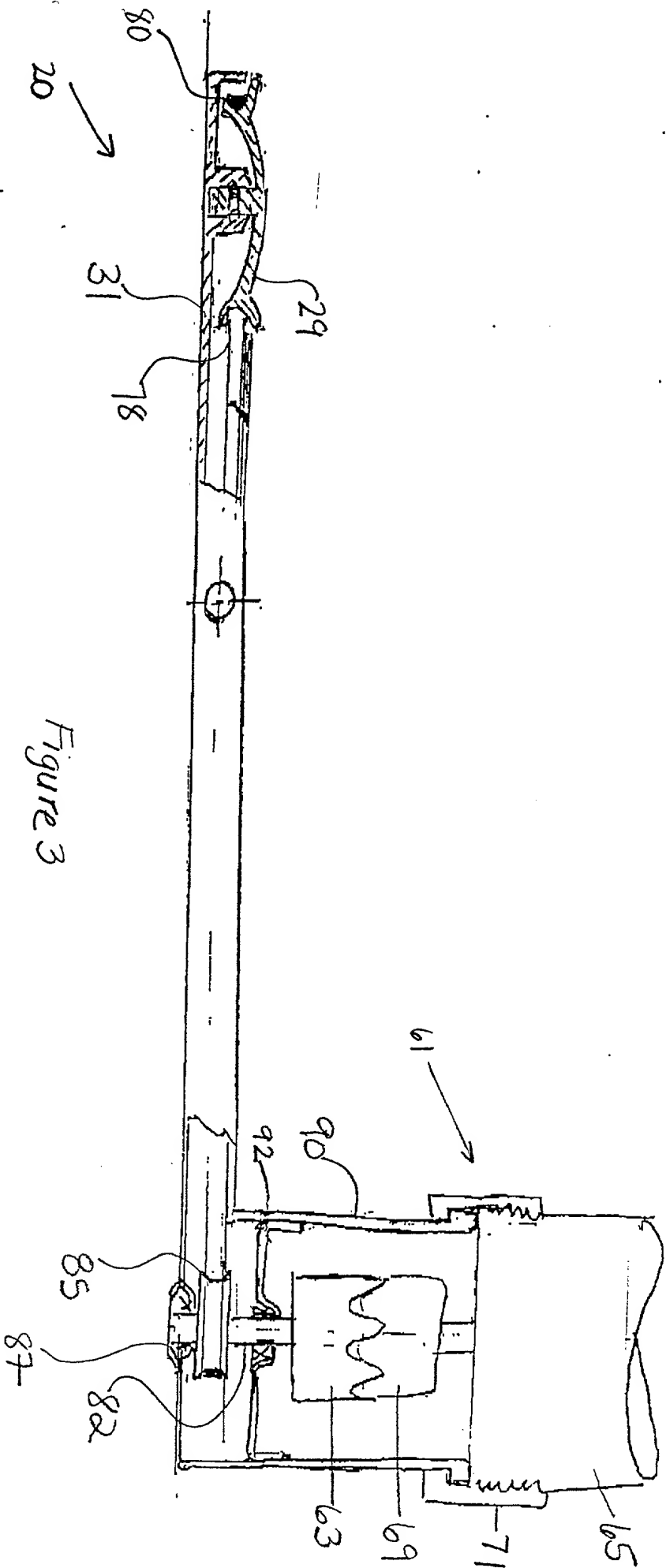


Figure 3

Docket No.
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Declaration and Power of Attorney For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

DRILL HEAD FOR USE IN PLACING AN INTERVERTEBRAL DISC DEVICE

the specification of which

(check one)

☒ is attached hereto.

☐ was filed on _____ as United States Application No. or PCT International Application Number _____ and was amended on _____ (if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Priority Not Claimed

_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/>
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/>
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/>

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

_____ (Application Serial No.)	_____ (Filing Date)
_____ (Application Serial No.)	_____ (Filing Date)
_____ (Application Serial No.)	_____ (Filing Date)

I hereby claim the benefit under 35 U. S. C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112. I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, C. F. R., Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

_____ (Application Serial No.)	_____ (Filing Date)	_____ (Status) (patented, pending, abandoned)
_____ (Application Serial No.)	_____ (Filing Date)	_____ (Status) (patented, pending, abandoned)
_____ (Application Serial No.)	_____ (Filing Date)	_____ (Status) (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 CFR 1.9(f) AND 1.27 (c)) - SMALL BUSINESS CONCERN**

Docket No.
P1178USA

Serial No.

Filing Date

Patent No.

Issue Date

Applicant/ Bryan, Vincent; Kunzler, Alex
Patentee:

Invention: **DRILL HEAD FOR USE IN PLACING AN INTERVERTEBRAL DISC DEVICE**

I hereby declare that I am:

- ☒ the owner of the small business concern identified below;
☐ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN: Spinal Dynamics Corporation

ADDRESS OF CONCERN: 15400 S.E. 30th Place, Bellevue, Washington 98007

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the above identified invention described in:

- ☒ the specification filed herewith with title as listed above.
☐ the application identified above.
☐ the patent identified above.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed on the next page and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 CFR 1.9(c) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- ☒ no such person, concern or organization exists.
☐ each such person, concern or organization is listed below.

FULL NAME
ADDRESS

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME
ADDRESS

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME
ADDRESS

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME
ADDRESS

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING:

Vincent Bryan

TITLE OF PERSON SIGNING

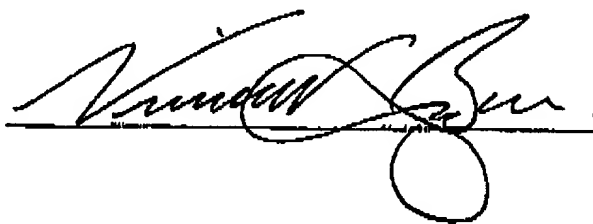
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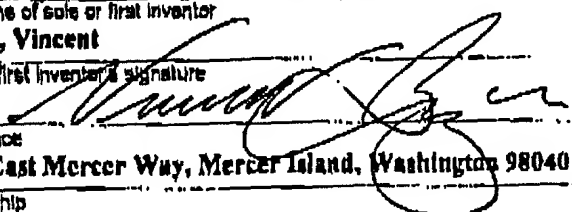
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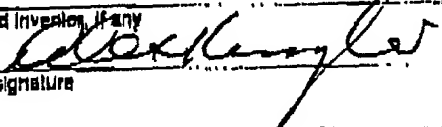
POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(list name and registration number)*

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